

Nuclear Regulatory Commission

§ 35.406

record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 59 FR 61784, Dec. 2, 1994; 62 FR 4133, Jan. 29, 1997]

§35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

[51 FR 36951, Oct. 16, 1986, as amended at 54 FR 41821, Oct. 12, 1989]

§35.404 Release of patients or human research subjects treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient or human research subject surveys for three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

[59 FR 61785, Dec. 2, 1994]

§35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's or the human research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for three years.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61785, Dec. 2, 1994]

§35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61785, Dec. 2, 1994]

§35.415 Safety precautions.

(a) For each patient or human research subject receiving implant therapy and not released from licensee con-

trol pursuant to §35.75 of this part, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy.

(2) Post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61785, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994; 62 FR 4133, Jan. 29, 1997]

§35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.